

C. Remarks

The claims are 1-14 and 15-41, with claims 1, 2, 19 and 20 being independent. Claim 15 has been cancelled without prejudice or disclaimer and its subject matter has been added to claims 1 and 2. Applicants submit that no new matter has been added. Reconsideration of the present claims is respectfully requested.

Claims 1-3, 6-8, 10 and 12-18 stand rejected under 35 U.S.C. §103(a) as being obvious over Borkan (U.S. Patent No. 4,935,243) or Hassan (WO 03/090726) in view of Tindal (U.S. Patent No. 6,387,400) and Tanner (U.S. Patent No. 6,340,473). Applicants respectfully traverse this rejection.

The present invention is directed to an edible, chewable, soft gelatin capsule; importantly, the capsule shell is formed from a capsule film having a wet mass comprising at least gelatin, hydroxypropylated, substantially ungelatinized starch and glycerol. By virtue of this constitution, it is possible to provide high water content, chewable soft gelatin capsules with improved organoleptic properties. The present invention allows for the manipulation of the origin, bloom strength and melting points of gelatins and mixtures of gelatins, the use of substantially ungelatinized starch as a water retention agent, the fabrication of thinner than expected gelatin films for use in the encapsulation process, only partial drying to a high end water content and dusting of the capsules with an anti-stickiness surface treatment agent. As set forth in the amended independent claims (and therefore applicable to all dependent claims), the capsule shell is formed from a capsule film (ribbon) having a thickness not exceeding 0.030 inches.

One research goal behind the instant invention was to increase heat stability, at least in part by exploring gelatins of higher bloom strength and mammalian origins, while maintaining the excellent organoleptics seen in fish gelatins with low bloom strengths, low melting points, and/or high water contents. Page 5, lines 17-21. Applicants found that higher bloom strengths allow for the casting of thinner films such as that presently claimed, which results in faster dissolution/disintegration of the capsule shell. Page 13, lines 5-10. Additionally, higher bloom gelatins allow for stronger and more robust ribbons. Page 13, lines 7-9. Therefore, a unique aspect of the present claimed invention is that the gelatin capsules are able to maintain both robust seals and thin walls (in accordance with the newly added claim limitation) by virtue of the combination of stronger gelatins and hydroxypropylated, substantially ungelatinized starch. Page 13, lines 13-21.

Borkan discloses a chewable softgel capsule containing gelatin and a plasticizer (including glycerol); however, as noted by the Examiner, Borkan contains no teaching or suggestion with regard to the inclusion of a starch or other water retentive agent in an ungelatinized or crystalline form. The hydrogenated starch hydrolysate used therein (described at column 4, line 5, to column 5, line 11) is characterized as a mixture of sugars, hydrogenated sugars, polyols and sugar alcohols. This component in no way equates with the high molecular weight, polymeric starch employed in the subject invention. Additionally, unlike the present claimed invention, Borkan fails to disclose or suggest the thickness of the capsule film as presently claimed. Further, there is no teaching or suggestion that bloom strength may relate to the thickness of the capsule film.

Hassan likewise relates to a chewable softgel capsule, which incorporates a matrix or fill system, which is gelled or semi-gelled, formed from a gelatin, a gelatin modifier and, in some cases, a hydrolyzed gelatin. This matrix is then encapsulated in a relatively conventional sheath or outer capsule shell. Here again, as indicated by the Examiner, Hassan contains no teaching or suggestion of the addition of a starch or other water retentive agent or any matrix forming component in an ungelatinized or crystalline form to the capsule shell as required by the subject invention. In fact, as noted previously, Hassan addresses a technology very different from the present invention, i.e., a softgel with a gelled fill material, and simply would not have led one of ordinary skill in the art to the composition of the softgel capsule of the present claimed invention. In any event, Hassan fails to disclose or suggest the presently claimed thickness of the capsule film, and not unlike Borkan, Hassan fails to make any teaching regarding a relationship between gelatin bloom strength and capsule film thickness.

Neither Tindal nor Tanner remedies the deficiencies of Borkan and Hassan. The Examiner alleges that Tindal teaches a soft gelatin capsule comprised of a gelatin, a plasticizer and an anti-adhesion agent. However, unlike the disclosure of the use of hydroxypropylated starch (HPS) in the present claimed invention, Applicants submit that, because Tindal contains only a passing reference to HPS as one of a number of possible components for the casing or shell material, and there is no reference to the use of the HPS in an ungelatinized or partially crystallized form, Tindal cannot be said to render the use of HPS in the present invention obvious. The present claimed invention specifically claims HPS and realizes the benefits of such which were not appreciated by Tindal.

Furthermore, Tindal generally relates to the partial neutralization of a drug incorporated into a fill system by the addition of sequential aliquots of the neutralizing agent. There is no teaching or suggestion of a particular shell composition suitable for a chewable capsule. The Examiner has incorrectly cited Tindal as evidence for the use of glycerol as a plasticizer, but it is actually disclosed as a co-solvent for the active pharmaceutical agent. As with Hassan, one of ordinary skill in the art would not rely on this reference for any teachings related to the formulation of a chewable softgel shell. Tindal would not suggest to one of ordinary skill in the art the softgel capsule of the present claimed invention. In any event, Tindal fails to disclose or suggest the presently claimed thickness of the capsule film, and not unlike Borkan and Hassan, Tindal fails to make any teaching regarding a relationship between gelatin bloom strength and capsule film thickness.

Tanner discloses capsule shell compositions comprising iota carrageenan, modified starch (including HPS) and plasticizer (including glycerol). However, there is no reference to the use of gelatin and, indeed, the disclosure states that the intention is to obviate the requirement for gelatin. As such, this reference teaches away from the present invention wherein modified starch and plasticizer are combined with gelatin. In other words, one of ordinary skill in the art would not be motivated to combine this reference with Borkan or Hassan to achieve the subject invention (which requires the use of gelatin).

According to M.P.E.P. § 2145 X.(D.)(2.), "it is improper to combine references where the references teach away from their combination." Since Tanner teaches away from a capsule shell composition using gelatin, it may not properly be combined with

references teaching such a gelatin-based composition. Therefore, Applicants submit that Tanner may not properly be cited in combination with Borkan or Hassan to argue that the subject invention is obvious.

In sum, the presently claimed invention is not rendered obvious by the cited references, whether considered separately or in any permissible combination. Both Borkan and Hassan fail to disclose or suggest at least the use of hydroxypropylated, substantially ungelatinized starch and a ribbon thickness of less than 0.030 inches. Further, Tindal and Tanner fail to remedy these deficiencies. For at least these reasons, Applicants submit that the present invention is not rendered obvious and respectfully request withdrawal of the §103 rejection.

In view of the foregoing amendments and remarks, favorable reconsideration and passage to issue is earnestly requested. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicants' undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

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